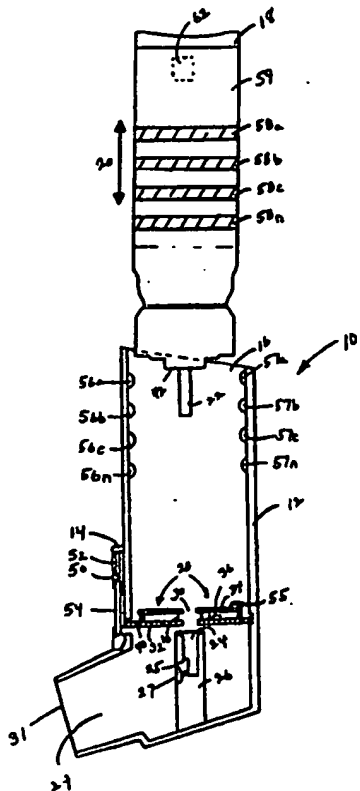




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁵ : A61M 11/00</p>	<p>A1</p>	<p>(11) International Publication Number: WO 92/17231 (43) International Publication Date: 15 October 1992 (15.10.92)</p>
<p>(21) International Application Number: PCT/US92/02555 (22) International Filing Date: 27 March 1992 (27.03.92) (30) Priority data: 676,274 28 March 1991 (28.03.91) US (71) Applicant: INNOMED, INC. [US/US]; 7200 Wisconsin Avenue, Suite 402, Bethesda, MD 20814 (US). (72) Inventors: HAVER, Kenan ; Two Hawthorne Place, Apt. 6D, Boston, MA 02114 (US). BRADNER, Scott, O. ; 15 High Street, Cambridge, MA 02138 (US). BOSTON, Matthew, R. ; 1082 W. Schafer Drive, Tucson, AZ 85705 (US).</p>		<p>(74) Agent: NABINGER, Robert, C.; Fish & Richardson, 225 Franklin Street, Boston, MA 02110-2804 (US). (81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), LU (European patent), MC (European patent), NL (European patent), SE (European patent). Published With international search report.</p>
<p>(54) Title: MICROELECTRONIC INHALER HAVING A COUNTER AND TIMER</p> <p>(57) Abstract</p> <p>A medical inhaler (10) featuring a microelectronic assembly (14), a receptacle (16) for a container (18) of medication. A triggering element (28) electrically coupled to the microelectronic assembly (14), positioned inside the receptacle (16) and activated by pressing the container (18) to release a dose of medication. The microelectronic assembly (14) may be a counter (54), or an interval timer for recording the dosage history of the container, including time intervals between doses. The inhaler includes electrical contact fingers (56a-56n and 57a-57n) contacting an electrical circuit (52) on the container (18) which stores information about the container (18) in digital form. The digital data storage means includes a set of electrically conductive strips (58a-58n) on the container (18) whose spatial pattern represents data about the container (18), and a microelectronic memory. The digital data stored includes the number of doses remaining, the time interval between doses previously actuated, the type of medication, the expiration date, the lot and serial number of the container (18), and other usage information.</p> 		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	CN	China	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	RU	Russian Federation
CG	Congo	KP	Democratic People's Republic of Korea	SD	Sudan
CH	Switzerland	KR	Republic of Korea	SE	Sweden
CI	Côte d'Ivoire	LJ	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
DE	Germany	MC	Monaco	TG	Togo
DK	Denmark			US	United States of America

- 1 -

"MICROELECTRONIC INHALER HAVING A COUNTER AND TIMER"**Background of the Invention**

This invention relates to medical inhalers.

5 Many people suffer from airway diseases that are amenable to treatment with aerosolized medications. Such medications are often delivered through inhalers that include a receptacle for an aerosol container of the medication and a passage through which the medication is
10 delivered from the container to the airways of a patient through either the nose, mouth, or other means. Typically the aerosol container includes a predetermined number of doses of the medication. Each dose of medication is actuated by depressing the aerosol
15 container, which releases a single dose of medication into the inhaler passage.

Summary of the Invention

In general, in one aspect, this invention features a microelectronic assembly, including a microprocessor,
20 coupled to the body of a medical inhaler having a receptacle for receiving a container of medication and an inhalation passage for delivering a dose of medication to a patient. A triggering element, such as a pressure switch or an optical switch, is electrically coupled to
25 the microelectronic assembly, and is positioned inside the receptacle so that it is activated by pressing the container to release a dose of medication. The pressure switch includes a sealed dome switch, a membrane switch, a Hall-effect device, or a pair of electrical contacts
30 sandwiched between a rigid member and a flexible member in contact with the container. A container detector, such as a switch, is also electrically coupled to the microelectronic assembly, and is positioned in the receptacle so that it is activated by a medicine
35 container being placed into the receptacle.

- 2 -

In another aspect, the microelectronic assembly is configured as a counter, responsive to the triggering element, for counting the number of doses of medication actuated from the container. The microelectronic assembly includes a display for displaying information such as the number of doses already actuated from the container, or the number of doses remaining in the container. The microelectronic assembly may also include an audible signal generator for generating audible signals when, for instance, a predetermined number of doses of medication have been actuated and the container is running low.

In another aspect, the microelectronic assembly is configured as an interval timer, responsive to the triggering element, for timing the interval between doses of medication actuated. The display may indicate the time interval since the last dose was activated. The microelectronic assembly also records the dosage history of the container, including the time intervals between doses, for later playback and analysis.

In yet another aspect, the inhaler includes a group of electrical contact fingers disposed in the receptacle for contacting an electrical circuit on the container. The electrical circuit on the container stores information about the container in digital form which is accessed by the microelectronic assembly through the contact fingers.

In general, in one aspect, the invention features a medication container for use with an inhaler including a digital data storage means for storing data about the container. In one embodiment, the digital data storage means includes a set of electrically conductive strips on the container whose spatial pattern represents data about the container. The electrically conductive strips are

- 3 -

electrically coupled to the inhaler by a set of contact fingers in the inhaler receptacle.

In another aspect, the digital data storage means includes a microelectronic memory, such as a non-volatile electronic memory or a battery backed-up electronic memory, attached to the container and electrically coupled to a set of electrically conductive strips on the container. An inhaler is electrically coupled to the microelectronic memory through a set of electrically conductive contact fingers inside the inhaler receptacle contacting the electrically conductive strips on the container. An inhaler so connected may read from, and write to, the electronic memory.

In yet another aspect, the data stored in the digital data storage means represents a history of use of the medical container, including the number of doses remaining in the container, and the time interval between doses previously actuated from the container. The digital data also represents other information such as the type of medication in the container, the expiration date, the lot and serial number of the container, and other usage information.

Description of Preferred Embodiments

A brief description of the drawings is as follows.

FIG. 1 is a front view of a medical inhaler with a microelectronic assembly according to this invention.

FIG. 2 is a side view of the medical inhaler taken along lines 2-2 of FIG. 1.

FIG. 3 is a top view of the medical inhaler taken along lines 3-3 of FIG. 1, also showing, in phantom, a medicine container in place in the inhaler receptacle.

FIG. 4 is a cross-sectional view of the medical inhaler taken along lines 4-4 of FIG. 1, also showing the medicine container, according to this invention, outside the inhaler receptacle.

- 4 -

FIG. 5 is a view of the medical inhaler of FIG. 4, also showing the medicine container in place inside the inhaler receptacle.

FIGS. 6a and 6b are side views of the medicine container, according to this invention, showing electrically conductive strip patterns representing different binary data words.

Structure

Referring to the FIGS. 1 - 5, medical inhaler 10 includes plastic body 12 and microelectronic assembly 14. Plastic body 12 has a receptacle 16 with one open end sized and shaped to receive a pressurized aerosol medication container 18 (FIGS. 4 and 5), which slidably engages (arrow 20, FIG. 4) inside the receptacle. Container 18 has an outlet nozzle 22 that press-fits into an opening 24, against a stop 25, in collar 26, which protrudes from a wall of plastic body 12. Collar 26 also includes spray opening 27, through which a dose of medication is released in aerosol form when pressure is applied to the bottom of container 18 such that the container is displaced relative to the nozzle 22. Spray opening 27 directs the released dose into inhalation passage 29 for inhalation out of plastic body 12 through open end 31.

A pressure switch assembly 28 (FIGS. 4 and 5) traverses receptacle 16 adjacent to collar 26, and has a central opening 30 sized and shaped to permit outlet nozzle 22 of container 18 to pass through it and into opening 24 in collar 26. A cutout 29 (FIG. 3) on each side of central opening 30 provides an aperture through which air may be drawn during inhalation. Pressure switch assembly 28 includes a backing plate 32 made of stiff plastic material and supported between microelectronic assembly 14 and a wall of plastic body 12. A flexible printed circuit board 34 lies parallel to

- 5 -

and above backing plate 32, and a metal switch contact 36 is sandwiched between circuit board 34 and backing plate 32. Switch contact 36 is positioned opposite an electrical trace on circuit board 34 so that flexing the circuit board causes the switch contact to make an electrical connection to the trace on the circuit board.

Pressure switch 28 is sealed around the perimeter of opening 30 by a polymer membrane 38 which surrounds the opening and is attached between circuit board 34 and backing plate 32. An outer support member 40 is also attached between the circuit board and the backing plate, and surrounds polymer membrane 38 and metal switch contact 36. The polymer membrane and the outer support member together provide flexible support for circuit board 34 and a watertight seal for switch contact 36.

Other types of sealed electrical switches are also available to implement pressure switch assembly 28. They include sealed dome switches, wire mesh type membrane switches, Hall-effect devices, and optical switches.

Pressure switch assembly 28 is electrically connected to microelectronic assembly 14 and acts as an electrical triggering element providing a "dose actuated" signal for the microelectronic assembly. Microelectronic assembly 14 includes a plastic housing 50, attached to an outer surface of body 12, enclosing microprocessor electronics 52, and a liquid crystal display 54 (FIG. 1). Microprocessor electronics 52 may include a microprocessor and its associated read only and random access memories, a real time clock module and a battery.

An optional reset switch 55, which is a sealed electrical switch of the type described above, is located on circuit board 34 outside the contact area of medication container collar 42. Reset switch 55 is electrically connected to microprocessor electronics 52 for resetting the electronics when the switch is

- 6 -

activated. The reset switch is activated by removing the medicine container from receptacle 16 and using the end of an elongated object, such as a pencil, to traverse the length of the receptacle and depress the switch.

5 Medical inhaler body 12 also includes two sets of resilient in-line electrically conductive contacts, or fingers, 56a - 56n and 57a - 57n (four fingers are shown in each set for illustration purposes but a larger quantity may be desirable) which protrude from an inner
10 wall of plastic body 12 into receptacle 16 and resiliently contact the side of aerosol container 18 when the container is engaged into the receptacle (FIG. 5). Each electrically conductive contact is electrically connected to microelectronic assembly 14 to enable the
15 microprocessor electronics to access data stored in digital form on container 18. Fingers 56a - 56n are disposed in-line along the length of plastic body 12 so that they align with and contact at most a like number of circular electrically conductive strips, or patterns, 58a
20 - 58n on the label 59 of container 18. Each finger is uniquely positioned opposite a corresponding strip location and contacts that corresponding strip if present, e.g., finger 56a contacts strip 58a, finger 56b contacts strip 58b, etc.. Similarly, fingers 57a - 57n
25 are disposed in-line along the length of plastic body 12 opposite fingers 56a - 56n, respectively, so that finger 57a also contacts strip 58a, finger 57b also contacts strip 56b, etc.. Thus, an electrical circuit is formed between any finger 56x (x representing a...n) and its
30 corresponding finger 57x when the corresponding electrically conductive strip 58x is present on the label 59. For instance, one electrical circuit will be formed between finger pairs 56b and 57b when conductive strip 58b is present on the label, and another will be formed

- 7 -

between finger pairs 56c and 57c when conductive strip 58c is present on the label.

Referring also to FIGS. 6a and 6b, the pattern of electrically conductive strips 58a - 58n on container label 59, formed by strips and extra spaces between strips (i.e., missing strips), corresponds to the digital pattern of a data word stored on a particular container. Each strip 59x present on the label forms an electrical circuit between its corresponding finger pairs 56x and 57x which is detected by microelectronic assembly 14. Thus, the finger pairs that contact an electrically conductive strip indicate an electrical short circuit, or logic "0", to microelectronic assembly 14, while the finger pairs that do not contact an electrically conductive strip (i.e., contact a space otherwise available for an electrically conductive strip) indicate an electrical open circuit, or logic "1", to the microelectronic assembly. For example, the pattern of electrically conductive strips shown in FIG. 6a represent the binary data word "0101" since (assuming that strip location 58a represents the least significant bit of the data word) strips 58b and 58n present an electrical short circuit, logic "0", for the second and fourth bit locations, and the absent strips 58a and 58c (shown in phantom) present an electrical open circuit, logic "1", for first and third bit locations. Similarly, the pattern of electrically conductive strips shown in FIG. 6b represent the binary data word "0110".

The presence of a medication container engaged in receptacle 16 of the inhaler is detected by microelectronic assembly 14 whenever at least one conductive strip 58x contacts a pair of fingers 56x and 57x to produce a logic "1". Alternatively, if only the lowermost finger pairs 56n and 57n are used to detect that a container is engaged in receptacle 16, and all

- 8 -

containers have conductive strip 58n present, then microelectronic assembly 14 will only detect containers that are fully engaged, i.e., properly seated, within the receptacle.

- 5 In alternative embodiments, a similar finger pair and conductive strip configuration is used as a power switch for supplying power to microelectronic assembly 14, thereby only powering the inhaler electronics when a medicine container is engaged in the receptacle. As
10 another alternative, a separate pressure switch, electrically connected to microelectronic assembly 14 and mounted on inhaler wall 12 so as to contact the container, is used to detect the presence of a container engaged in the receptacle or supply power to the
15 microelectronic assembly 14.

Use

- Medication container 18, which typically holds a predetermined number of metered doses of medication, is inserted into receptacle 16 with aerosol nozzle 22
20 resting against stop 25 in opening 24 of collar 26. Electrically conductive strips 58a - 58n present on label 59 align with and contact finger pairs 56a - 56n and 57a - 57n, respectively. Microelectronic assembly 14 senses the presence of container 18 engaged in receptacle
25 16 through the alignment of particular conductive strips with particular finger pairs.

- A patient directs the end 29 of the inhaler with opening 31 into his or her mouth and applies pressure to the exposed end of container 18 to release a metered
30 dosage of medication from the container, through opening 31, and into his or her mouth. Concurrently, the applied pressure causes the shoulder 42 of container 18 to bear against and flex circuit board 34, causing switch contact 36 to contact the circuit board to complete an electrical

- 9 -

circuit, thereby signaling microelectronic assembly 14 that a single dose has been actuated.

The microprocessor electronics 52 of microelectronic assembly 14 may be configured to provide a variety of functions. When, for instance, the microprocessor electronics is configured to act a dose counter, the "dose actuated" signal is processed in accordance with instructions, stored in the electronic memory associated with microprocessor electronics 52, to track the quantity of doses actuated. The dose counter may be configured as either an up-counter, for accumulating the total number of doses actuated, or as a down-counter, for subtracting each dose actuated from a predetermined quantity of available doses. Each "dose actuated" signal received by the microelectronic assembly is used to increment or decrement the dose counter, depending on its configuration. The current doses actuated count, for the up-counter configuration, or the current doses available quantity, for the down-counter configuration, is displayed on microelectronic assembly display 54.

Prior to the first dose actuated from a new medicine container placed in receptacle 16, microprocessor electronics 52 is initialized in accordance with its functional configuration. If, for instance, the microprocessor is configured to act as an up-counter, the counter is initialized to 0, and if configured as a down-counter, the counter is initialized to the maximum metered dosage available from a new (full) medicine container 18. Microprocessor electronics 52 may be initialized during the manufacturing process of the inhaler, since a newly manufactured inhaler is typically supplied to the patient with each new medicine container, and is meant to be used only with that container. Optionally, reset switch 55 may be activated to

- 10 -

initialize the microprocessor electronics before a new medicine container is installed into the receptacle of the inhaler.

The patient monitors the number of doses used from, or remaining in, the medication container by using the display. The microprocessor may also be configured to alert the patient when the container is almost empty. When all doses in the container have been used, the patient may simply remove the used container, activate the reset switch 55 to cause the microprocessor to initialize the counter function, and install a new medicine container.

Additionally, the microprocessor electronics, if configured as a timer or used in conjunction with a clock circuit, keeps track of the interval between actuated doses, and informs the patient that the interval is too short, or that another dose is due to be taken, depending on the circumstances. The microprocessor electronics may also store the dosage history of the patient for later playback and assessment by, for example, the patient's physician.

Further, finger pairs 56a - 56n and 57a - 57n present a digital data word to the microprocessor circuit 52 of microelectronic assembly 14 corresponding to the pattern of electrically conductive strips 58a - 58n encoded on label 59 of container 18. Microprocessor electronics 52 responds to this data word in accordance with instructions stored in its associated electronic memory. The size of the data word (i.e., the number of bits of digital information) determines the quantity of information it conveys. Thus, increasing the quantity of finger pairs 56a - 56n and 57a - 57n increases the quantity of patterns available for electrically conductive strips 58a - 58n to take, thereby increasing the information conveyed about the container to the

- 11 -

microprocessor electronics. For instance, the information encoded by the strips may indicate to the microprocessor the type of medication in the container, dosage interval limitations, container serial number, expiration date, etc.. With this information the microprocessor can keep track of each container used with a particular inhaler, alert the patient to dosage limitations and expiration, and provide a more detailed medication history for use by the patient's physician.

10 Inhalers are typically sold by pharmaceutical companies along with a specific medication. Representative examples include Alupent® metered dose inhaler and Atrovent® inhaler, available from Boehringer Ingelheim; Ventolin® inhalation aerosol, Beconase® nasal inhaler and Beclovent® inhalation aerosol, available from 15 Glaxo; AeroBid® inhaler system, available from Forest; Medihaler® ergotamine, available from Riker; Azmacort™ inhaler, available from Rorer Pharmaceuticals; Metaprel® inhalation aerosol, available from Sandoz; Proventil® 20 inhaler, Vanceril® inhaler and Vancenase® nasal inhaler, available from Schering; and, Intal® inhaler and Intal® spinhaler turbo-inhaler, available from Fisons. Representative examples of other types of metered dosage medication delivery systems which may benefit from this 25 invention include Beconase® AQ nasal spray, and Ventolin Rotacaps® for inhalation, available from Glaxo; and, Vacanase® AQ nasal spray, available from Schering.

Other Embodiments

Another embodiment of inhaler 10 provides for 30 communications between microelectronic assembly 14 and an active microelectronic element 62 attached to each container 18. Microelectronic element 62 is, for instance, a non-volatile electronic memory, or a battery backed-up memory, embedded under label 59. Fingers 56a -

- 12 -

56n (or 57a - 57n) and electrically conductive strips 58a - 58n provide a bus-type electrical connection between microelectronic element 62 and microelectronic assembly 14 to allow microprocessor electronics 52 to
5 read and update microelectronic element 62. Each container 18 would store its own "personality profile" which would travel with the container as an integral part of it, independent of the particular inhaler used with it. Thus, microelectronic element 62 could, for
10 instance, record the type of drug in the container, the number of doses left in the container, the dosage history of the container, the drug lot, serial number and expiration date of the container, and, in general, provide a detailed history of the container to the
15 patient and physician.

Other embodiments are within the following claims. For example, a standard audible signal generator can be included in the microelectronic assembly to signal the patient as determined by the particular application. The
20 positioning of the electronic switches, electrically conductive strips and associated contact fingers may be altered, for instance, providing the electrically conductive strips as concentric rings on the shoulder of the container and positioning the contact fingers on the
25 pressure switch. The division of electronics between the inhaler and the container may also be altered. For instance, the microprocessor electronics may be mounted on the container, and the inhaler only provides battery power and display, or all the electronics including the
30 battery and display are mounted on the container. Moreover, the pressurized or non-pressurized container can deliver medication in the form of a non-aerosolized liquid.

- 13 -

Claims

1 1. An inhaler comprising
2 a body having a receptacle, adapted to receive a
3 medication container, and an inhalation passage connected
4 to said receptacle through which a dose of medication can
5 be inhaled; and
6 a microelectronic assembly coupled to said body
7 for monitoring the use of the medication.

1 2. The inhaler of claim 1 wherein said
2 microelectronic assembly includes a microprocessor.

1 3. The inhaler of claim 1 further comprising
2 a triggering element electrically connected to
3 said microelectronic assembly, said triggering element
4 disposed to be activated when a dose of medication is
5 actuated.

1 4. The inhaler of claim 3 wherein
2 the medication container is an aerosol container
3 actuated by applying an activation pressure to the
4 container, and
5 said triggering element senses said activation
6 pressure.

1 5. The inhaler of claim 4 wherein
2 said triggering element includes an pressure
3 switch disposed in said receptacle and adapted for being
4 acted upon by one end of the medication container so that
5 a portion of said activation pressure is transferred to
6 activate said pressure switch.

1 6. The inhaler of claim 5 wherein said pressure
2 switch includes
3 a rigid portion disposed stationary to said body,

- 14 -

4 a flexible portion opposite said rigid portion and
5 adapted to be operated upon by one end of the medical
6 container, and

7 at least two electrical contacts disposed between
8 said rigid portion and said fixed portion, said contacts
9 being electrically connected to said microelectronic
10 assembly;

11 wherein said activation pressure causes
12 displacement of said flexible portion toward said rigid
13 portion thereby causing contact between said electrical
14 contacts.

1 7. The inhaler of claim 5 wherein said pressure
2 switch includes a dome switch.

1 8. The inhaler of claim 5 wherein said pressure
2 switch includes a membrane switch.

1 9. The inhaler of claim 5 wherein said pressure
2 switch includes a Hall-effect device.

1 10. The inhaler of claim 4 wherein
2 said triggering element includes an optical switch
3 disposed in said receptacle and adapted for sensing the
4 movement of the medication container in response to said
5 activation pressure.

1 11. The inhaler of claim 10 wherein said optical
2 switch includes an LED.

1 12. The inhaler of claim 10 wherein said optical
2 switch includes a photocell.

1 13. The inhaler of claim 3 wherein

- 15 -

2 said microelectronic assembly functions as a
3 counter responsive to said triggering element for
4 counting the doses of the medication actuated from the
5 container.

1 14. The inhaler of claim 13 wherein
2 said microelectronic assembly includes a display
3 for displaying an indication of the expected number of
4 doses of medication available from the container.

1 15. The inhaler of claim 14 wherein
2 said display indicates a count of the doses of
3 medication actuated from the container.

1 16. The inhaler of claim 14 wherein
2 said display indicates a count of the expected
3 quantity of doses of medication remaining to be actuated
4 from the container.

1 17. The inhaler of claim 13 wherein
2 said microelectronic assembly further comprises an
3 audible signal generator that provides an audible signal
4 in response to said counter.

1 18. The inhaler of claim 17 wherein
2 said counter causes said audible signal generator
3 to provide an audible signal after a predetermined number
4 of doses of medication have been actuated from the
5 container.

1 19. The inhaler of claim 3 wherein
2 said microelectronic assembly is configured as a
3 timer responsive to said triggering element for counting
4 the time interval between doses of medication actuated
5 from the container.

- 16 -

1 20. The inhaler of claim 19 wherein
2 said microelectronic assembly includes a display
3 for indicating said time interval.

1 21. The inhaler of claim 3 further comprising
2 a container detector electrically connected to
3 said microelectronic assembly, said container detector
4 disposed to be activated by the presence of a medication
5 container in said receptacle.

1 22. The inhaler of claim 21 wherein
2 said container detector comprises a pressure
3 switch disposed in said receptacle and adapted to contact
4 a container placed in said receptacle.

1 23. The inhaler of claim 1 further comprising
2 a plurality of electrical contact fingers disposed
3 in said receptacle and adapted to contact a pattern of
4 electrical conductors on the medication container, said
5 contact fingers being electrically connected to said
6 microelectronic assembly.

1 24. The inhaler of claim 23 wherein
2 said electrical contact fingers comprise a
3 plurality of contact finger pairs, each said contact
4 finger pair comprising two spaced electrical contact
5 fingers adapted to contact the same electrical conductor,
6 the electrical conductor providing an electrical circuit
7 between said contact fingers of said contact finger pair.

1 25. The inhaler of claim 23 wherein
2 said electrical contact fingers electrically sense
3 digital data stored on the medication container, and

- 17 -

4 said digital data is processed by said
5 microelectronic assembly.

1 26. The inhaler of claim 25 wherein
2 said digital data corresponds to the type of
3 medication in the container and said microelectronic
4 assembly is configured to function dependent on said
5 medication type.

1 27. The inhaler of claim 25 wherein
2 said digital data corresponds to the number of
3 doses remaining in the container and said microelectronic
4 assembly is configured to function dependent on the
5 number of doses remaining.

1 28. A medicine container for use with an inhaler,
2 comprising
3 a container body for storing medicine, said
4 container body having an aerosol nozzle at one end and
5 adapted to fit the receptacle of an inhaler, and
6 digital data storage means for storing data about
7 said container, said storage means being accessible by
8 said inhaler.

1 29. The medicine container of claim 28 wherein
2 said digital storage means comprises a plurality
3 of electrically conductive strips on said container body,
4 said electrically conductive strips disposed to align
5 with and electrically connect to a plurality of
6 electrical contact fingers in the inhaler receptacle.

1 30. The medicine container of claim 29 wherein
2 said electrically conductive strips are disposed
3 on a label placed on said container body.

- 18 -

1 31. The medicine container of claim 29 wherein
2 said digital data is stored by the pattern of
3 electrically conductive strips laid down on said
4 container body.

1 32. The medicine container of claim 28 wherein
2 said digital storage means comprises a pattern of
3 electrically conductive and electrically insulating
4 regions on said container body, said electrically
5 conductive regions disposed to align with and
6 electrically connect to a first plurality of electrical
7 contact fingers disposed in the inhaler receptacle, and
8 said electrically insulating regions disposed to align
9 with and electrically insulate a second plurality of
10 electrical contact fingers disposed in the inhaler
11 receptacle..

1 33. The medicine container of claim 32 wherein
2 said electrically conductive and electrically
3 insulating regions are disposed on a label placed on said
4 container, said label comprising an electrically
5 conductive medium and a pattern of insulating strips laid
6 down on said conductive medium to define said
7 electrically conductive and said electrically insulating
8 regions.

1 34. The medicine container of claim 28 wherein
2 said digital data storage means comprises a
3 microelectronic memory circuit disposed on said container
4 body, and
5 said container further comprises electrical
6 connection means for electrically connecting said
7 microelectronic memory circuit to the inhaler.

1 35. The medicine container of claim 34 wherein

- 19 -

2 said electrical connection means comprises a
3 plurality of electrically conductive strips on said
4 container body, said electrically conductive strips
5 disposed to align with and electrically connect to a
6 plurality of fingers in the inhaler receptacle.

1 36. The medicine container of claim 34 wherein
2 said microelectronic memory circuit comprises a
3 non-volatile memory which may be read from and written to
4 by said inhaler.

1 37. The medicine container of claim 34 wherein
2 said microelectronic memory circuit comprises a
3 battery-backed up electrical memory which may be read
4 from or written to by the inhaler.

1 38. The medicine container of claim 36 wherein
2 said digital data represents a history of use of
3 said medical container.

1 39. The medicine container of claim 38 wherein
2 said history of use includes the expected number
3 of medicine doses remaining in said container.

1 40. The medicine container of claim 38 wherein
2 said history of use includes a record of the time
3 intervals between said medicine doses previously actuated
4 from said container.

1 41. The medicine container of claim 28 wherein
2 said digital data represents the type of medicine
3 in said container.

1 42. The medicine container of claim 28 wherein

- 20 -

2 said digital data represents the expiration date
3 of the medicine in said container.

1 43. The medicine container of claim 28 wherein
2 said digital data represents usage information
3 about the medicine in said container.

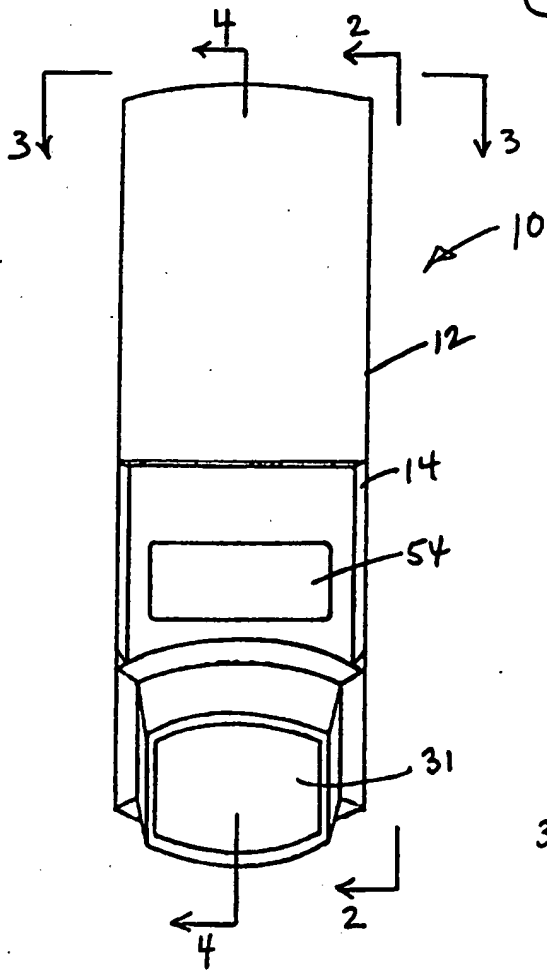
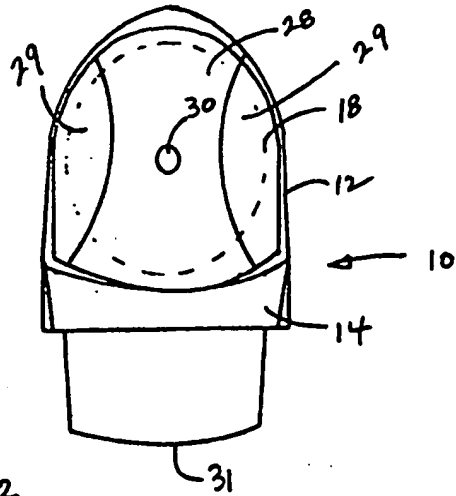


FIG. 1

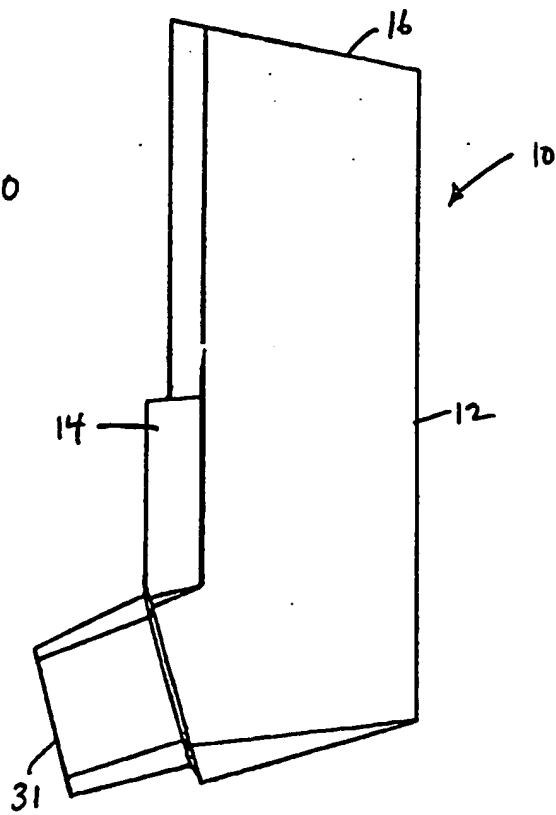


FIG. 2

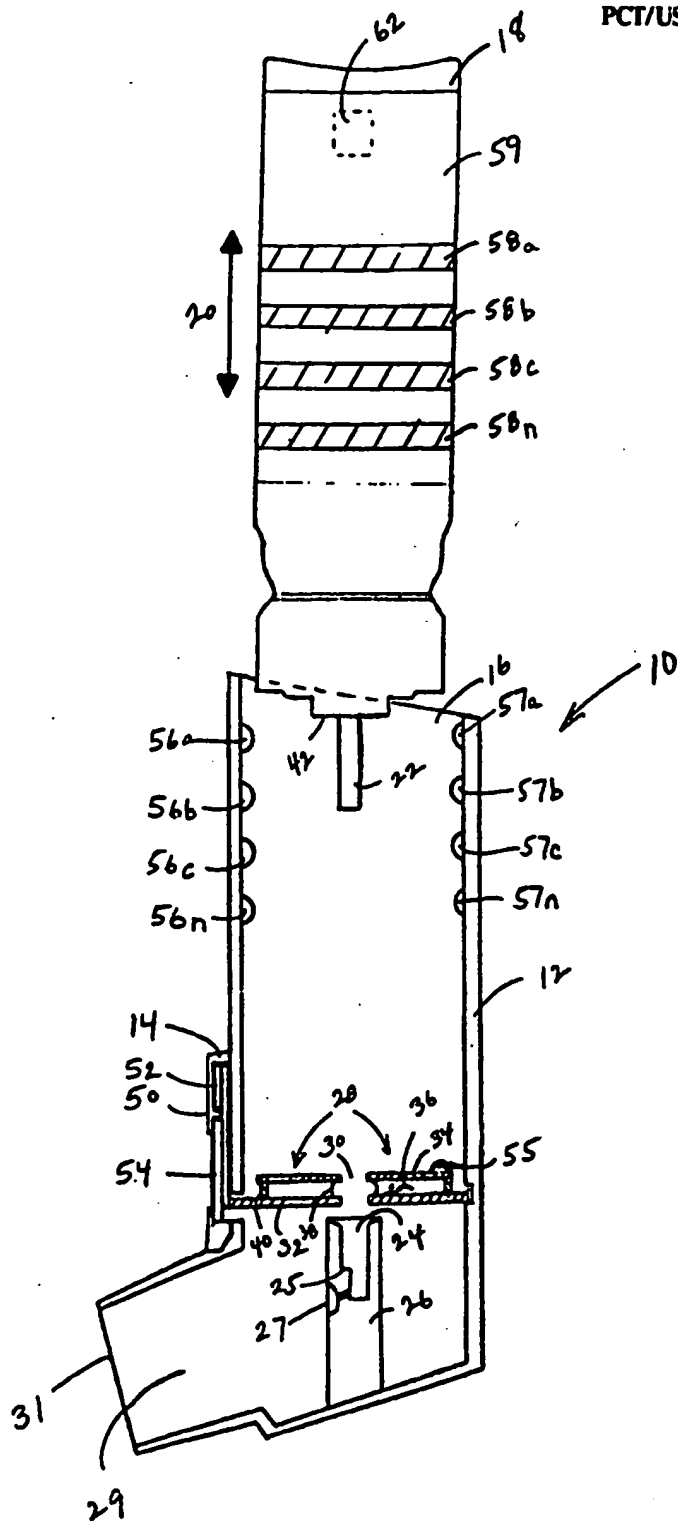


FIG. 4

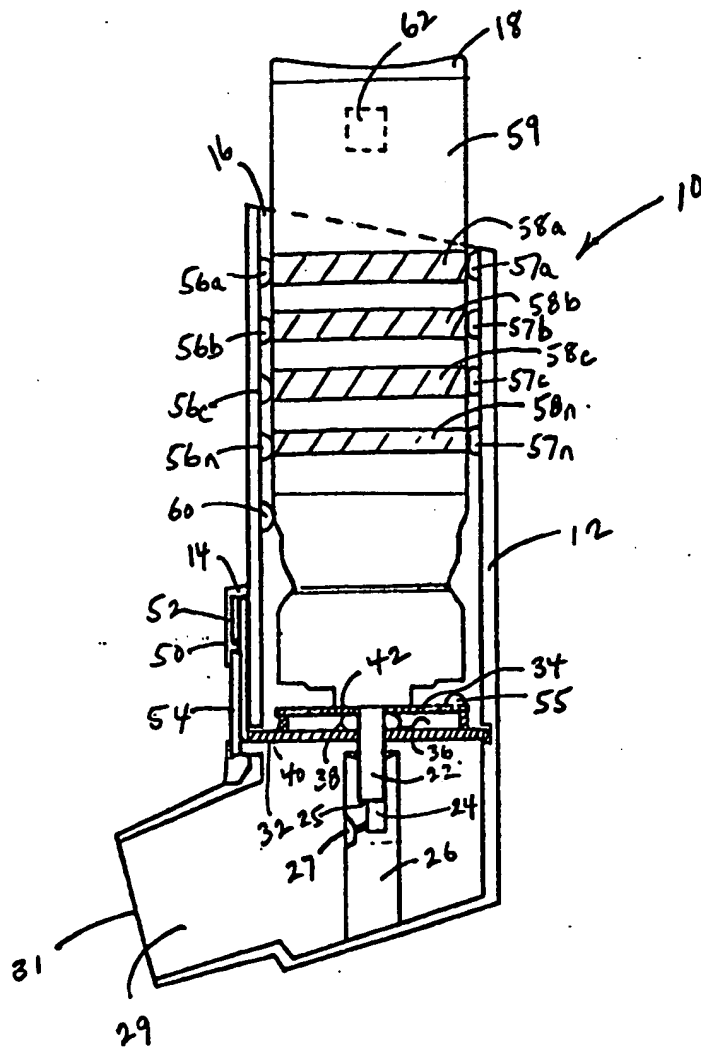


FIG. 5

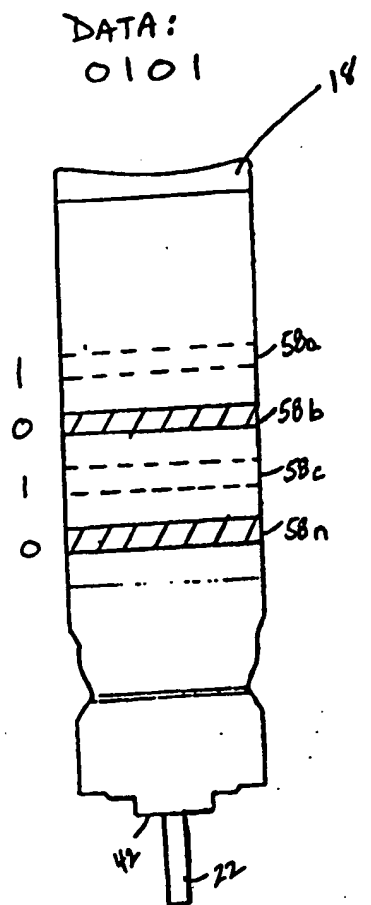


FIG. 6a

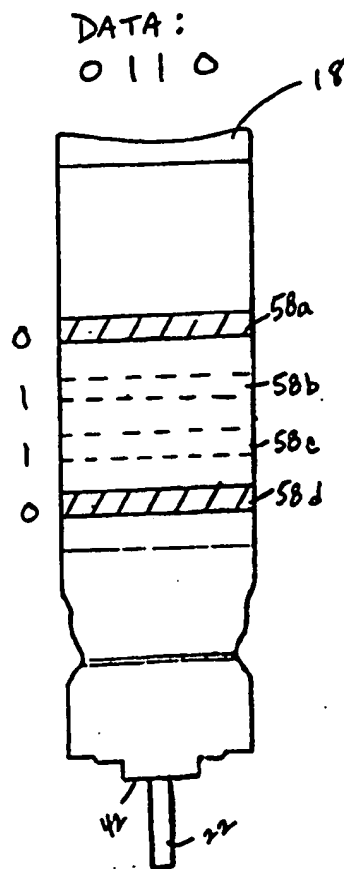


FIG. 6b

INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US92/02555**

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) * According to International Patent Classification (IPC) or to both National Classification and IPC I.P.C.(5): A61M 11/00 U.S. Cl: 128/200.14, 200.23						
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched ?</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%; border: 1px solid black; text-align: left;">Classification System</th> <th style="border: 1px solid black; text-align: left;">Classification Symbols</th> </tr> <tr> <td style="border: 1px solid black; vertical-align: top; padding: 5px;">U.S.</td> <td style="border: 1px solid black; padding: 5px;">123/200.14 - 200.19, 200.21 - 200.24, 203.12 - 203.15, 205.23</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched *</div>			Classification System	Classification Symbols	U.S.	123/200.14 - 200.19, 200.21 - 200.24, 203.12 - 203.15, 205.23
Classification System	Classification Symbols					
U.S.	123/200.14 - 200.19, 200.21 - 200.24, 203.12 - 203.15, 205.23					
III. DOCUMENTS CONSIDERED TO BE RELEVANT *						
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **				
X Y	US, A 4,934,358 (NILSSON ET AL), 19 June 1990. See entire document.	1-4, 13, 19 5-12, 14-18, 20-43				
Y, P	US, A 5,020,527 (DESSERTINE), 04 June 1991. See entire document.	5-12, 14-18, 20				
Y	US, A 4,693,853 (FALB ET AL), 15 September 1987. See entire document.	21-43				
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: *</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"A" document member of the same patent family</p> </div> </div>						
IV. CERTIFICATION						
Date of the Actual Completion of the International Search 19 May 1992	Date of Mailing of this International Search Report <div style="text-align: center; font-size: 1.2em;">23 JUN 1992</div>					
International Searching Authority ISA/US	Signature of Authorized Officer <div style="display: flex; align-items: center;"> <div style="flex: 1;"> Kimberly L. Asher <small>INTERNATIONAL DIVISION</small> </div> <div style="flex: 1; text-align: right;"> <i>Nguyen</i> </div> </div>					

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.